

SUBJECT: Abbreviated Construct Hazard Assessment for J15-31

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\*\*\*\*\* [REDACTED] \*\*\*\*\*

## I. INTRODUCTION

The Agency has received a Microbial Commercial Activity Notice (MCAN) from Danisco US, Inc. (operating as DuPont Industrial Biosciences) for an intergeneric *Saccharomyces cerevisiae* strain that has [REDACTED]. In a previous submission [REDACTED] the recipient *S. cerevisiae* strain was modified by the introduction of a [REDACTED]. In the current submission, a [REDACTED] resulting in the new submission strain [REDACTED]. The parental strain is *S. cerevisiae* [REDACTED] strain used in fuel ethanol production that has [REDACTED]. [REDACTED] that can then be fermented into ethanol by the microorganism. The production microorganism, strain [REDACTED], will thus be used for production of fuel ethanol from grain.

## II. POTENTIAL HAZARDS POSED BY THE GENETIC MODIFICATIONS

Genetic modifications of the recipient strain to arrive at the submission strain, *S. cerevisiae* [REDACTED] are described in detail by Segal (2015) in the Genetic Construction Report.

### A. Inserted Genes

There is low hazard associated with the introduced [REDACTED] gene to create the submission strain of [REDACTED]. The introduced [REDACTED] gene [REDACTED]. [REDACTED] have a long history of safe use in the food industry. [REDACTED] is

common in microorganisms and [REDACTED]  
[REDACTED] which can then be fermented into ethanol.

There is low hazard associated with the introduced [REDACTED] gene to create the submission strain *S. cerevisiae* [REDACTED]. This enzyme is [REDACTED] and is also found in humans and other mammals. The donor microorganism, [REDACTED], is ubiquitous in the environment in soils, water, and vegetation. It has a long history of safe use for [REDACTED]

## **B. Potential for Horizontal Gene Transfer**

The introduced genes were both stably inserted into the chromosome which means they are unlikely to horizontally transfer to other microorganisms in the environment if the submission microorganism was inadvertently released from the manufacturing facility or ethanol production plants. The scientific literature suggests that horizontal gene transfer (HGT) between fungi is low even though recently it has been suggested that HGT of genes from other organisms into fungi has been shown to be important in the evolution of fungi (Rosewich et al., 2000; Fitzpatrick, 2004; Richards et al., 2011). There is low concern for horizontal gene transfer, and there would be low concern even if the genes were to be transferred.

## **III. CONCLUSIONS**

There are low hazards associated with the genetic modifications done to create the submission strains, *S. cerevisiae* [REDACTED]. The introduced [REDACTED] are commonly found in many microorganisms and merely allow for the [REDACTED]. These [REDACTED] do not pose hazards. Also there is low potential for horizontal gene transfer if the submission microorganism was inadvertently introduced into the environment.

## **REFERENCES**

Fitzpatrick, D.A. 2012. Horizontal gene transfer in fungi. FEMS Microbiol. Letters 329:1-8.

[REDACTED]

Richards, T.A., G. Leonard, D.M. Soanes, and N.J. Talbot. 2011. Gene transfer into the fungi. Fungal Biology Reviews 25:98-110.

Rosewich and Kistler. 2000. Role of horizontal gene transfer in the evolution of fungi. Annu. Rev. Phytopathol. 38:325-63.

Segal, M. 2015. Genetic Construction Report for J15-31. Office of Pollution Prevention and Toxics. U.S. Environmental Protection Agency, Washington, DC.